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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,373	06/21/2002	Isao Ishida	051023-0115	3667

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EXAMINER

TON, THAIAN N

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/049,373

Applicant(s)

ISHIDA ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See *Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1,3-5,9 and 25.
Claim(s) withdrawn from consideration: 6, 10-24.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 6/21/06
13. ☐ Other: _____.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Continuation of 3. NOTE: The proposed claim amendments raise new issues that require further search and consideration with regard to compounds that induce the expression of a human cytochrome CYP3A4 family gene. In particular, although the prior Office action recites that the mice are inducible by rifampicin (see page 7, last paragraph of the Office action mailed 3/21/06), the proposed claim amendments are directed to embodiments that are outside of this scope, and thus, would require a new search and/or consideration.

Continuation of 11. does NOT place the application in condition for allowance because: The proposed claim amendments are not entered, therefore the prior rejections of record are maintained. To the extent that Applicants' arguments are pertinent to the rejections of record, the Examiner addresses these below.

Enablement. Applicants argue that the chromosomal fragment, E22, is not essential for making the claimed invention, because any chromosomal fragment that possess the recited cytochrome genes can be incorporated into the claimed mouse. A mouse that comprises the Ohshima chromosomal fragment instead of the E22 fragment is not inoperative simply because its chromosomal termini are different, and that the important patentable issue is that both the E22 and Ohshima fragment comprise the same recited cytochrome genes, which are subsequently expressed in the mouse cell, when exposed to a compound, such as rifampicin. Applicants argue that the specification fully enables and supports the mouse of claim 1. see pages 7-9 of the Response.

These arguments are considered, but not persuasive. The Examiner maintains that the E22 fragment is essential to the claimed invention, because the phenotype of the mouse is directly influenced by the gene(s) that are incorporated into its genome. Thus, the phenotype of the mouse, as is instantly claimed, and any of its resultant phenotypes are dependent upon the fragment used. There is no guidance or teachings with regard to mice that are produced with other fragments, and the resultant phenotype of those mice. Accordingly, it is maintained that the E22 fragment is essential to the claimed invention, with regard to the deposit of this fragment, and that once this deposit is perfected, the claims will be limited to the deposited E22 fragment.